UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,406	05/29/2001	John Clark Lagarias	407T-907720US	7073

22798 7590 07/15/2003

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	19

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,406	LAGARIAS ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group III (claims 33-38) in Paper No. 13 is acknowledged. Applicants have elected HY2 as a species and not as a patentably distinct invention. The traversal is on the ground(s) that the various bilin reductases in claims 1-19 are species and are not patentably distinct inventions. This is not found persuasive because although the individual bilin reductase were not identified by groups, the Restriction Requirement clearly indicates that Group III comprises of many different patentably distinct bilin reductases. A detailed grouping of the individual bilin reductases follows which can be substituted under the general umbrella of the Groups I-VII.

Group A) claims 1-4 and 8-10, drawn to a PebAbilin reductase as shown in Figure 5.

Group B) claims 1-4, 8-9 and 11, drawn to a PebAbilin reductase as shown in Figure 5.

Group D) claims 1 and 5-7, drawn to a bilin reductase as shown in Figure 10.

Group E) claims 12-20, drawn to a HY2_ARATH bilin reductase.

Group F) claims 12-16 and 17-20, drawn to a YCP2_SYNPY bilin reductase.

Group G) claims 12-18, drawn to a YHP2_PROMA bilin reductase.

Group H) claims 12-18, drawn to a YHP3_PROMA bilin reductase.

Group I) claims 12-16 and 17-20, drawn to a YCP3_SYNPY bilin reductase.

Group J) claims 12-20, drawn to a SLR0116 bilin reductase.

Group K) claims 12-20, drawn to a PcyA_ANASP bilin reductase.

Group L) claims 12-20, drawn to a PcyA_NOSPU bilin reductase.

Group M) claims 12-20, drawn to a PcyA_SyNY3 bilin reductase.

Group N) claims 12-20, drawn to a PcyA_SYN8.1 bilin reductase.

Group O) claims 12-20, drawn to a PcyA_PROME bilin reductase.

Group P) claims 12-20, drawn to a PebA_SYNPY bilin reductase.

Group Q) claims 12-20, drawn to a PebA_SYN8.1 bilin reductase.

Group R) claims 12-20, drawn to a PebA_PROMA bilin reductase.

Group S) claims 12-20, drawn to a PebA_PROME bilin reductase.

Group T) claims 12-18, drawn to a PewbB_NOSPU bilin reductase.

Group U) claims 12-15 and 17-20, drawn to a RCCR_ARATH bilin reductase.

Group V) claims 12-15 and17-20, drawn to a RCCR_HORVU bilin reductase.

Group W) claims 19-20, drawn to a PebA_NOSPU bilin reductase.

Group X) claims 19-20, drawn to a PebB_SYNPY bilin reductase.

Group Y) claims 19-20, drawn to a PebB_SYN8.1 bilin reductase.

Group Z) claims 19-20, drawn to a PebB_PROMA bilin reductase reductase.

Group AA) claims 19-20, drawn to a PebB_PROME bilin reductase.

Group BB) claims 19-20, drawn to a PebB_NOSPU bilin reductase.

Group CC) claims 19-20, drawn to a athy2 bilin reductase.

Group DD) claims 19-20, drawn to a c362_anab bilin reductase.

The above bilin reductases are patentably distinct because they are different in structure, substrate specificity, and physical and chemical properties.

Applicants also argue that restriction between Group I and III is unnecessary since the DNA of Group III encodes the bilin reductases. As stated in the Restriction Requirement, DNA and proteins are patentably distinct inventions because the two compounds are physically and functionally distinct chemical entities.

Claims 1-34 and 39-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Claim Objections

Claim 35 is objected to as being dependent upon a non-elected base claim, and should be rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 35 is objected to as being dependent upon a non-elected base claim. However for the interest of a compact prosecution, claim 35 has been interpreted with the limitations of claim 19. Examiner notes that claim 19 is drawn to non-elected inventions.

Specification

The disclosure is objected to because of the following informalities: the brief description of the drawings on page 12 of the specification refers to Figure 3A but there is no corresponding Figure 3A in the Drawings.

Appropriate correction is required.

Drawings

The drawings are objected to because Figure 3B is not preceded by a figure 3A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. Claims 35-36 read on a product of a human cell.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 35-38 are drawn to a nucleic acid molecule encoding a HY2 bilin reductase. Therefore, these claims are drawn to a genus of HY2 bilin reductase, with any structure and from any source. Art teach that HY2 bilin reductase is not well known in the art, but the specification only teaches one representative species, SEQ ID NO:33, from *Arabidopsis thaliana*. One representative species is not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of an *Arabidopsis thaliana* HY2 bilin reductase and the structure of a HY2 bilin reductase from another source. Therefore, the specification fails to describe other representative species of the genus of HY2 bilin reductase.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 35-38.

Claims 35-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid molecule encoding the HY2 bilin reductase of SEQ ID NO: 33, does not reasonably provide enablement for a nucleic acid molecule encoding a HY2 bilin reductase not homologous to SEQ ID NO:33. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Despite knowledge in the art for the isolation of polynucleotides, the specification fails to provide guidance regarding how to isolate other polynucleotides encoding HY2 bilin reductase whose sequence is not homologous to SEQ ID NO:33. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other carbonyl reductase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make nucleic acid molecule encoding a HY2 bilin reductase not homologous to SEQ ID NO:33 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 35, which ultimately depends from claim 19, the phrase "conservative substitutions thereof" is confusing. It is not clear if the claim is drawn to a HY2 bilin reductase having conservative amino acid substitutions or if the claim is drawn to bilin reductase that is homologous or equivalent to the HY2 bilin reductase.

In claims 37-38, the exact hybridization condition is unclear. Different nucleic acids hybridize to a DNA sequence under different conditions. Therefore, the scope of DNA molecules in claims 37-38 is unclear.

In claim 37, the mere recitation of the name "hvrccr" or "atrccr" is insufficient to convey with clarity that which applicant sees as the invention.

In claim 38, the phrase "wherein said nucleic acid is a vector" is confusing because nucleic acids are not normally hybridized with vectors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 35 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Lin et al.

Lin et al. teach a nucleic acid sequence encoding a HY2 polypeptide that is 100% identical to SEQ ID NO:33 of the instant invention (See Sequence Search). Therefore, the teaching of Lin et al. anticipates claims 35 and 37.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. in view of Hollis et al.

Lin et al. teach a nucleic acid molecule encoding a HY2 bilin reductase, as discussed above.

The difference between the reference of Lin et al. and the instant invention is that the reference of Lin et al. does not teach a vector or host cell comprising said DNA.

Hollis et al. (U.S. Patent No. 5,538,885) teach expression systems comprising mammalian host cells transformed with vectors containing DNA encoding heterologous proteins (abstract and Columns 1-2). The expression systems of Hollis et al. is capable of expressing polypeptides at high levels and secreting the polypeptides expressed (Column 2).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use the expression system of Hollis et al. to

express the HY2 bilin reductase encoded by the nucleic acid molecule of Lin et al. The motivation of using the expression system of Hollis et al. is to efficiently produce the recombinant enzyme rather than by standard biochemical purification methods. One of ordinary skill in the art would have had a reasonable expectation of success since expression of heterologous proteins in mammalian host cells are performed routinely in the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

July 10, 2003

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600